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09/680,465	10/06/2000	Daniel A. Japuntich	48317USA11.028	8753

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EXAMINER

LEWIS, AARON J

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/680,465

Applicant(s)  
DANIEL A. JAPUNTICH ET AL.

Examiner  
AARON J. LEWIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 26, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 33, 35-57, 59-63, and 66-80 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33, 35-57, 59-63, and 66-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## DETAILED ACTION

### *Double Patenting*

1. Claims 33,35-57,59-63,65,66 of this application conflict with claims 34-44 of Application No. 08/240,877; 33-71 of 09/678,579; 34-77 of 09/440,619; 33-58,60-67 of 09/678,580; 33-54,56-61 of 09/678,488; 33-54,56 of 09/677,637; 33-36,38-62,64-66 of 09/677,636. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 33,35-46,48-57,59,66-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al.('516) in view of McKim('618).

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As to claim 33, Simpson et al. disclose a filtering (page 1, lines 108-113) face mask (1,2) that comprises: a mask body (1,2) that is adapted to fit over the nose and mouth of a wearer (fig. 1); and an exhalation valve (12) that is positioned on the mask body substantially opposite to a wearer's mouth, the exhalation valve comprising: a valve seat that comprises: a seal surface (page 2, lines 37-50 and #19) and an orifice (16) that is circumscribed by the seal surface; cross members (surfaces between orifices 16) that extend across the orifice to create a plurality of openings within the orifice; and a single flexible flap (15) that has a fixed portion (page 2, lines 46-50) and only one free portion and first and second opposing ends (page 2, lines 42-50), the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with only the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person (fig. 1), wherein the flexible flap is positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith when fluid is not passing through the orifice (page 2, lines 41-50).

The difference between Simpson et al. and claim 33 is the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it, but the flexible flap when secured to the valve seat at its fixed portion has a curved profile when viewed from a side elevation.

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McKim ('618) teaches a flexible flap which would normally assume a flat configuration when not secured to the valve seat and having no forces applied to it, but the flexible flap when secured to the valve seat at its fixed portion (14a) has a curved profile when viewed from a side elevation. McKim teaches a curved seal surface and curved flexible flap for the purpose of seating quickly, effectively and without float or bounce after each opening (col.1, lines 64-72). Additionally, the one free portion of the flexible flap of Simpson et al. as further modified by McKim (figs.1,5) has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

It would have been obvious to modify the flexible valve flap and seat of Simpson et al. (fig.2) to be curved because it would have provided quick seating, in an effective manner and without float or bounce after each opening as taught by McKim.

As to claims 35-36, the valves (figs.2 and 3) of Simpson et al. (page 2, lines 37-65) are disclosed as being made of plastic and/or rubber material. It would have been obvious to fabricate the valves by any well known technique which is known to be employed in the fabrication of plastics and rubber including the technique of injection molding.

As to claim 37, Simpson et al. disclose the flexible flap being pressed towards the seal surface such that there is a substantially uniform seal when the valve is in a closed position (page 2, lines 39-42). The seal (figs.2 and 3) of Simpson et al. are illustrated as being substantially uniform and since the flexible flap (15) of Simpson et al. is disclosed of being made from plastic and since known physical characteristics of plastics include flexibility and resiliency, the flap (15) of

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Simpson et al. being made from plastic is fully capable of providing the recited function of "...capable of allowing the flap to display a bias towards the seal surface."

As to claim 38, the flexible flap (15) of Simpson et al. is disclosed as being made of flexible plastic and as such is fully capable of performing the recited function of resisting permanent set and creep.

As to claims 39 and 42, the flexible flaps (15,18) of Simpson et al. is disclosed as being made of plastic and/or rubber for example (page 2, lines 39 and line 53). It would have been obvious to make the flexible flap from any well known flexible material including an elastomeric rubber such a polyisoprene as mere substitution of one well known flexible material for another and because elastomeric rubber is a well known material from which to make valve flaps.

As to claims 40 and 41, the degree of a seal between the valve flap and valve seat sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30 C.F.R. 11.183-2, July 01, 1991. Further, it stands to reason that one ordinary skill in the art would strive to make a face mask in accordance with at least minimum current government standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 43-46, <sup>47,</sup>48,49, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through

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mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency.

As to claim 50, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts including 10-25% fixed and 75-90% free.

As to claim 51, the flange against which the valve flap is secured in Simpson et al. (fig.2) is illustrated as being the same 360 degrees around the valve seat.

As to claim 52, given the downward orientation of the mask body (1,2) of Simpson et al. fig. 1 and given that any exhaled air must pass outward between the valve flap (15,14) and the body of the mask, it stands to reason that exhaled air will follow a path which is generally parallel to the upper surface of the body of the mask which itself is downwardly oriented as illustrated in fig. 1. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

As to claim 53, Simpson et al. (page 1, lines 116-123) disclose the mask body is cup-shaped and comprises at least one shaping layer for providing structure to the mask, and a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

As to claim 54-56, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, the valve of Simpson et al. is fully capable of providing the recited function inasmuch as it would remain opened as long as a

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wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Simpson et al..

As to claim 57, since the mask body (1,2) of Simpson et al. is angled downwardly when positioned on wearer's face, the valve (12) on mask body (1,2) of Simpson et al. is positioned substantially opposite a wearer's mouth (fig.1). The valve flap (15) of Simpson et al. is mounted on the valve seat (fig.2) in cantilever fashion.

As to claim 59, the shape of the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface inasmuch as the seal surface surrounds the orifice.

As to claim 66, Simpson et al. as further modified by McKim also teach a flexible flap having a curved profile when viewed from a side elevation in its secured position on the valve seat and is pressed towards the seal surface in an abutting relationship therewith (see figs. 1 and 5 of McKim).

As to claim 67, Simpson et al. as modified by McKim as discussed above with respect to claim 33 also teach a non-centrally disposed stationary segment and a only one free portion which are analogous to the abovementioned fixed portion and free portion of claim 33.

As to claim 68, the seal surface of each of Simpson et al. and McKim is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface (see col.1, lines 59,60 of McKim and figs.1,3).



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As to claim 69, the flexible flap (15) of Simpson et al. is disclosed as being made of flexible plastic and as such is fully capable of performing the recited function of resisting permanent set and creep.

As to claim 70, the degree of a seal between the valve flap and valve seat sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30 C.F.R. 11.183-2, July 01, 1991. Further, it stands to reason that one ordinary skill in the art would strive to make a face mask in accordance with at least minimum current government standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 71-74, the flexible flaps (15,18) of Simpson et al. is disclosed as being made of plastic and/or rubber for example (page 2, lines 39 and line 53). It would have been obvious to make the flexible flap from any well known flexible material including an elastomeric rubber such a polyisoprene as mere substitution of one well known flexible material for another and because elastomeric rubber is a well known material from which to make valve flaps and the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency.

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For example, the relative dimensions of the flap would depend upon the overall size of the mask (adult or child size) as well as on the desired volume of airflow intended to pass through the valve opening. The particular material and degree of hardness employed for the valve flap would depend how well the valve and seat material mated together to form a seal.

As to claim 75, given the downward orientation of the mask body (1,2) of Simpson et al. fig. 1 and given that any exhaled air must pass outward between the valve flap (15,14) and the body the of mask, it stands to reason that exhaled air will follow a path which is generally parallel to the upper surface of the body of the mask which itself is downwardly oriented as illustrated in fig. 1. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

As to claim 76, Simpson et al. (page 1, lines 116-123) disclose the mask body is cup-shaped and comprises at least one shaping layer for providing structure to the mask, and a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

As to claims 77 and 78, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, the valve of Simpson et al. is fully capable of providing the recited function inasmuch as it would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Simpson et al..

As to claim 79, since the mask body (1,2) of Simpson et al. is angled downwardly when positioned on wearer's face, the valve (12) on mask body (1,2) of Simpson et al. is positioned

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substantially opposite a wearer's mouth (fig.1). The valve flap (15) of Simpson et al. is mounted on the valve seat (fig.2) in cantilever fashion.

As to claim 80, the shape of the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface inasmuch as the seal surface surrounds the orifice.

4. Claims 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim as applied to claims 33,35-46,48-57,59,66-80 above, and further in view of Warbasse ('706) and Braun ('362).

The differences between Simpson et al. and claim 60 are an opening that is disposed directly in the path of fluid flow when a free portion of the flexible flap is lifted from the seal surface during an exhalation; a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end; and cross members that are disposed within the opening of the valve cover.

Warbasse teaches a valve cover (11) having a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end for the purposes of protecting the valve flap (12), controlling the extent of movement of the valve flap, and controlling the direction of fluid flow exiting the mask via the valve.

It would have been obvious to further modify the valve (fig.2) of Simpson et al. to provide a valve cover because it would have provided a means for protecting the valve flap (12), controlling the extent of movement of the valve flap, and controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse.

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Braun, in an exhalation valve for a filtering face mask, teaches cross members (25) that are disposed within the opening of the valve cover for the purpose of protecting the valve against debris (col.4, lines 25-26).

It would have been obvious to further modify the valve cover of Simpson et al. as modified by Warbasse to provide cross members within the opening of the valve cover because it would have provided a means for protecting the valve against debris as taught by Braun.

As to claim 61, Warbasse teach a valve cover (11 of fig.2) having an opening in the valve cover which is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

As to claim 62, Simpson et al. as further modified by Warbasse teach a cover which directs exhaled downwards when the mask is worn by a person.

As to claim 63, the cover (#11 of figs.2 and 3) of Warbasse shows fluid impermeable sidewalls.

5. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of McKim, Warbasse and Braun as applied to claims 60-63 above, and further in view of Shindel('277).

The difference between Simpson et al. as modified by McKim, Warbasse and Braun and claim 64 is the valve cover having a surface that holds the flexible flap against a flap-retaining surface on the valve seat.

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Shindel (col.2, lines 59-66) teaches a valve securing device in the form of a valve cover (7) that is disposed over the valve seat and that comprises a surface (14) that mechanically holds flexible flap (6) against the flap retaining surface (5). Shindel cites the advantages of simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices.

It would have been obvious to further modify the manner of attachment of the exhalation valve of Simpson et al. to employ a cover over having a flap retaining surface because it would have provided a simple arrangement with ready removability of the cover as taught by Shindel.

***Response to Arguments***


6. Applicant's arguments with respect to claims 33,35-57,59-63,65,66-80 have been considered but are moot in view of the new ground(s) of rejection.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Copies of all prior art references listed on the accompanying PTO-892 have been provided with the Office action in copending application 09/678,580.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

July 15, 2002

  
Aaron J. Lewis  
Primary Examiner